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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,539	07/31/2003	Matthew M. Winkler	AMBI:063US	2672

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,539	WINKLER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-116* is/are pending in the application.

4a) Of the above claim(s) *68-78,80-82,103 and 104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-67,79,83-102 and 105-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of species an affinity domain (which read on claims 52-67, 79, 83-102, 105-116 and a nucleic acid ligand (which reads on claims 52-116) in the reply filed on May 09, 2006 is acknowledged. Applicants' neither indicated whether the election is with traverse or without traverse and nor provided any arguments for traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status

2. Claims 52-67, 79, 83-102, 105-116 read on elected species and are considered for examination. Claims 68-78, 80-82, 103-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

Priority

3. This application filed on July 31, 2003 is a CON of PCT/US02/03097 filed on 1/30/2002, which claims benefit of 60/265,694 filed on 1/31/2001, CON of PCT/US02/03168 filed on 01/31/2002, CON of PCT/US02/02892 filed on 01/31/2002 which claims benefit of 60/265,695 filed on 1/31/2001, CON of PCT/US02/03169 filed on 01/30/2002 which claims benefit of 60/265,692 filed on 1/31/2001.

Information Disclosure Statement

4. The Information Disclosure Statement filed on November 03, 2003 has been entered and considered.

Specification

5. The following informalities were noted while reviewing the disclosure.

(i) the preliminary amendment filed on 7/31/2003 replaced beginning paragraph on page 1 of the instant disclosure, which contains blank lines for concurrently filed U.S. application No.

(ii) (ii) claim 93 recites 'complementary acids' , should have been 'complementary nucleic acids'.

Correction required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-67, 79, 83-101, 105-107, 113-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al. (EP 0 870 842).

Note: Claim 52 recites single-stranded targets in preamble of the claim, which is not given any patentable weight because according to MPEP 2111.02"[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003). In the context of claim 52, the method steps do not recite use of single stranded target nucleic acids therefore the preamble does not give life, meaning and vitality to the claim and therefore the preamble is not given any patentable weight.

Kato et al. teach a method of claims 52, 105, for comparing one or more nucleic acid targets within two or more samples comprising:

(a-d) preparing a sample mixture by a process comprising obtaining at least a first sample and a second sample, each potentially having at least a first nucleic acid target and mixing the first and the second nucleic acid sample to create a mixture (see page 2, line 48-52, page 7, line 1-57, page 8, line 1-45, page 9, line 41-55, page 10, line 1-57, page 11, line 1-3);

(c) performing co-amplification reaction on the first target and second target samples, wherein the amplification reaction produces at least a first amplified nucleic acid if the first nucleic acid target is present, and at least a second amplified nucleic acid, if the first nucleic acid is present in the second sample (see page 8, line 46-57, page 9, line 1-9, page 11, line 17-33);

(f) differentiating the first and second amplified nucleic acids present in the first target fraction, if any (see page 9, line 10-20, page 12, line 11-23);

(g) comparing abundance of the first amplified nucleic acid target of said first sample to the abundance of the first nucleic acid target of the said second sample (see page 9, line 20-37, page 12, line 24-40)

With regard to claims 52, 83-84, 105-106, Kato et al. also teach preparing tagged first and second nucleic acid samples (See page 8, line 1-39, page 10, line 10-57).

With regard to claim 52, 96-98, 105-106, Kato et al. teach that the method comprises preparing tagged first and second nucleic acid samples each tag comprises a differentiation domain (restriction enzyme recognition domain), mixing tagged first and second samples to create a mixture and performing a first amplification reaction on a first target fraction (see page 7, line 30-57, page 8, line 1-57, page 9, line 1-57).

With regard to claims 53, 57-63, Kato et al. teach that the tags are appended between amplification domain and the target sequence and the method comprises plurality of samples and

plurality of tags, wherein the tags are functional equivalent or identical to amplification domain (see page 2, line 25-36, page 10, line 1-57, indicating that the method comprises at least two samples and different adaptor tags having at least one restriction site, which reads on plurality of samples and tags).

With regard to claim 54-56, 58, 62-63, 99, 101, Kato et al. teach that the differentiation domain comprises an affinity domain, which are labeled (labeled adaptor has affinity to streptavidin-coated para-magnetic beads) (see page 8, line 1-57, page 10, line 1-57).

With regard to claims 64-67, 85-90, 92, 94-95, 99, Kato et al. teach that the first target fraction is isolated by binding a ligand (adaptor), which is a nucleic acid complementary to a segment of said target and said complementary nucleic acid is used to separate the first target from the plurality of the nucleic acid targets by binding it to a solid support (paramagnetic beads) (see page 8, line 1-57, page 10, line 1-57).

With regard to claims 100, Kato et al. teach that the differentiating comprises sequencing the amplified nucleic acids (see page 12, line 11-40, page 2, line 35-36).

Kato et al. teach a method of claim 79, 105, 113-116, for comparing one or more nucleic acid targets within two or more samples comprising:

(a-d) obtaining and preparing a sample mixture by a process comprising obtaining at least a first sample and a second sample, each potentially having at least a first nucleic acid target and mixing the first and the second nucleic acid sample to create a mixture (see page 2, line 48-52, page 7, line 1-57, page 8, line 1-45, page 9, line 41-55, page 10, line 1-57, page 11, line 1-3);

(e) isolating at least a first target fraction of the sample mixture (see page 8, line 45-46, page 11, line 5-15);

(f) performing at least a first amplification reaction on the first target fraction, wherein the amplification reaction produces at least a first amplified nucleic acid if the first nucleic acid target is present, and at least a second amplified nucleic acid, if the first nucleic acid is present in the second sample (see page 8, line 46-57, page 9, line 1-9, page 11, line 17-33);

(g) differentiating the first and second amplified nucleic acids present in the first target fraction, if any (see page 9, line 10-20, page 12, line 11-23);

(h) comparing abundance of the first amplified nucleic acid target of said first sample to the abundance of the first nucleic acid target of the said second sample (see page 9, line 20-37, page 12, line 24-40)

With regard to claim 105 Kato et al. also teach preparing tagged first and second nucleic acid samples (see page 8, line 1-39, page 10, line 10-57).

With regard to claim 106, Kato et al. teach that the differentiation domain comprises an affinity domain (see page 8, line 1-57, page 10, line 1-57).

With regard to claims 85-86, 107, Kato et al. teach that the first target fraction is isolated by binding a ligand, which is a nucleic acid complementary to a segment of said target and said complementary nucleic acid is used to separate the first target from the plurality of the nucleic acid targets by binding it to a solid support (paramagnetic beads) (see page 8, line 1-57, page 10, line 1-57). Accordingly the disclosure of Kato et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

> matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (EP 0 870 842) in view of Wang (US 6, 004, 755).

Kato et al. teach a method of comparing one or more nucleic acid targets within two or more samples as discussed above in section 6.

Although Kato teaches the use of a solid support, Kato did not specifically teach that the solid support is an array comprising plurality of complementary nucleic acids bound to said array.

Wang teaches a method for quantitative gene expression analysis using a microarray, wherein the array comprises plurality of complementary probe sequences bound to it (see col. 1, line 66-67, col. 2, line 1-10).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of comparing one or more nucleic acid targets as taught by Kato et al. with a step of using an array as taught by Wang for the purpose of

developing a sensitive high throughput assay format to compare the expression of plurality target nucleic acid. One skilled in the art would be motivated to combine the method as taught by Kato et al. in a manner taught by Wang by the inclusion of an array bound complementary nucleic acids because Wang explicitly taught the use of a microarray in screening gene expression of plurality of target sequences in a high throughput format and quantitating the genetic profile (see col. 1, line 6-32, line 66-67, col. 2, line 1-10). An ordinary artisan would have a reasonable expectation of success that inclusion of an array bound complementary sequences would result in a high throughput analysis of plurality of targets at a given time reducing the time to perform the method and use of reagents and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

B. Claim 102, 108-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (EP 0 870 842) in view of Carey (WO 00/05409).

Kato et al. teach a method of comparing one or more nucleic acid targets within two or more samples as discussed above in section 6.

Kato did not specifically teach the use of limiting concentration of a primer.

Carey teaches a method for quantitative analysis of gene expression using limiting primer concentrations for the targets (see page 5, line 5-28, page 6, line 1-19).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of comparing one or more nucleic acid targets as taught by Kato et al. with a step of using limiting concentrations of a primer as taught by Carey for the purpose of developing a sensitive for quantitation of gene expression levels. One skilled in the art would be motivated to combine the method as taught by Kato et al. in a manner taught

by Carey by the inclusion of limiting concentrations of a primer because Carey explicitly taught the use of a limiting concentration of a primer provides an efficient and time-saving solution for measuring two different target nucleic acids in a single sample (see page 6, line 24-28). An ordinary artisan would have a reasonable expectation of success that inclusion of a limiting concentration of a primer would result in a sensitive method for quantitating different targets at a given time reducing the time to perform the method and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru 7/23/06
SURYAPRABHA CHUNDURU
PATENT EXAMINER